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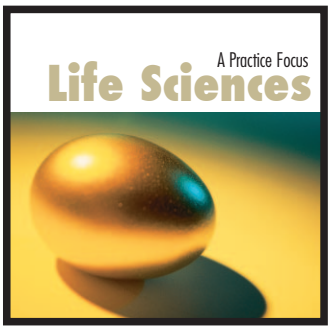
Must MedImmune Breach Before It Sues?

The Supreme Court will decide when a licensee can challenge a patent.

BY JOHN M. VASSILIADES

Must a patent licensee breach its license agreement before challenging the licensed patent? It's an important question, one that the Supreme Court has just agreed to resolve.

The case, which has been the subject of debate in the patent bar for several years already, is *MedImmune Inc. v. Genentech Inc.* The legal issue is whether a patent licensee must stop paying royalties before it can initiate a declaratory judgment action challenging the licensed patents.



Depending upon how the high court rules, the decision could dramatically affect the willingness of patent owners to grant patent licenses and the power of licensees to challenge those patents.

Paying Under Protest

The story behind *MedImmune v. Genentech* is itself very interesting. Genentech, in collaboration with the City of Hope National Medical Center, developed a recombinant DNA technology that makes antibody molecules. A U.S. patent was granted to Genentech on March 28, 1989. On the same day, Celltech R&D, a British company, also obtained a U.S. patent on similar antibody technology.

Before its patent was issued, Genentech had also filed a continuation application. Still pending in 1990, that application, which claimed the benefit of the date of the original patent application, was amended to restate the same claims as the Celltech patent.

The following year the U.S. Patent and Trademark Office declared an interference between Genentech and Celltech over which had priority—the Celltech patent or Genentech's continuation application. (The patents are also known by the names of their inventors, the Boss patent from Celltech and the Cabilly I patent and Cabilly II continuation patent from Genentech.)

While the interference was being disputed, MedImmune took a license from both Genentech and Celltech that, by its language, included the pending continuation application.

In 1998, soon after the Patent Office decided that Celltech had priority, Genentech sued in federal court to overturn that decision. But in 2001 a settlement and cross-licensing agreement was reached between the two parties, and that December the continuation application was finally issued as Patent No. 6,331,415 (the Cabilly II patent).

Now that Genentech and Celltech had resolved their priority dispute, Genentech informed MedImmune that its Synagis product (used to prevent serious respiratory tract disease in infants) was a "licensed product" under the Cabilly II patent and MedImmune owed royalties. MedImmune denied Genentech's claim for royalties but nevertheless paid under protest and with a reservation of all rights. The companies entered into agreements to license the 415 patent for other MedImmune products still under development.

Despite its status as a licensee in good standing, MedImmune soon thereafter filed a declaratory judgment action to invalidate the 415 patent and to receive a judgment of noninfringement by Synagis.

In 2004 the U.S. District Court for the Central District of California dismissed MedImmune's suit for lack of subject-matter jurisdiction. It based its ruling on the Federal Circuit decision that year in *Gen-Probe v. Vysis Inc.* In the Gen-Probe case the U.S. Court of Appeals for the Federal Circuit held that when a patent licensee complies with its royalty obligations, there is no "actual controversy" under the Declaratory Judgment Act and Article III of the Constitution.

Under *Gen-Probe*, a licensee must, at a minimum, stop paying royalties and thereby materially breach the license agreement to establish subject-matter jurisdiction. A license is essentially a covenant not to sue for infringement. There can be no "actual controversy," wrote the Federal Circuit, unless there is a "rea-

sonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit."

Applying *Gen-Probe*, the District Court held that controversies over patent validity, enforcement, and infringement would not be recognized while license agreements protected the licensee from suit for infringement. Because MedImmune was a licensee in good standing, it had no reasonable apprehension of being sued.

On appeal, the Federal Circuit affirmed the District Court's dismissal of MedImmune's suit. It concluded that something more than the obvious "adverse legal interests" between a licensor and a licensee was required to support federal jurisdiction.

Rather, there needed to be a "definite and concrete" controversy of "sufficient immediacy or reality" to justify judicial intervention. Since MedImmune "assiduously avoided breach" of its license by continuing to pay royalties under protest, MedImmune had no reasonable apprehension of being sued for infringement.

Reasons to Review

In its cert petition, MedImmune made two main arguments as to why the Supreme Court should review the lower court's decision.

First, MedImmune claimed that *Gen-Pro* was wrongly decided under past precedent. Specifically, the rule in *Gen-Pro,* which MedImmune characterized as requiring patent licensees to breach their license agreements to establish federal jurisdiction, was allegedly inconsistent with the purpose behind Article III and the Declaratory Judgment Act and with prior decisions of the Supreme Court and other federal circuit courts. MedImmune cited older Supreme Court precedent for the proposition that under Article III and the Declaratory Judgment Act, jurisdiction was established over disputes involving other types of contracts when there was no breach of contract, so long as there was real disagreement about the interpretation or scope of the contract.

According to MedImmune, adopting the *Gen-Pro* rule also distorted the principle of allowing access to the federal courts for actual controversies, because actual controversies can exist even without a breach. By holding otherwise in *Gen-Pro,* the Federal Circuit inappropriately divorced itself from other recent circuit decisions involving nonpatent licensees and general contracts. It allegedly departed as well from a line of older patent cases rendered in other circuit courts before patent appeals were consolidated in the Federal Circuit in 1982.

Most significant, MedImmune argued that *Gen-Pro* did not follow the Supreme Court's decision in *Lear v. Adkins*, a 1969 case made famous for the high court's hallmark ruling that (according to MedImmune) patent licensees can *never* be estopped from asserting their right to challenge the validity of the licensed patents.

MedImmune's second main point supporting Supreme Court review was its contention that unless licensees in good standing can challenge the licensed patents, patent owners will deliberately bundle their unrelated "bad patents" with their good or valid ones to extract an unfair price. Licensors know that licensees will be reluctant to challenge bundled "bad patents" for fear of being sued for infringement (with the attendant risks of treble damages and a business-stopping injunction) should they breach the license agreement over the "good patents."

Accordingly, unless the Supreme Court adopts MedImmune's proposed rule, innovation supposedly will suffer because others will be legally excluded from developing technologies protected by unworthy patents that go unchallenged by licensees in good standing.

Genentech's Side

Not surprisingly, in its opposition brief, Genentech offered a significantly different perspective on *Gen-Pro*.

Genentech stated, consistent with the Federal Circuit, that unless the licensee first breaches its license, there can be no reasonable apprehension of suit, and without such apprehension, there is no actual controversy and, therefore, no jurisdiction. The fear of being sued if a licensee were hypothetically to breach is not a "reasonable" apprehension.

Genentech further noted that many of the cases MedImmune cited involved some "additional factor," beyond the mere existence of a license or contract between the parties, that demonstrated the existence of a live controversy. Thus, the differing appellate decisions were generally attributable to the differences in the underlying facts and not to the Federal Circuit's refusal to follow established precedent.

Further, Genentech contended that *Gen-Pro* did not conflict with *Lear* because *Lear* had addressed only whether a licensee could challenge the validity of the patents when it was already being sued by the licensor for nonpayment of royalties. In other words, while *Lear* struck down the estoppel doctrine that previously prevented licensees from challenging licensed patents, it did not consider the question of when it was appropriate for licensees to challenge patents in a declaratory judgment proceeding.

With regard to the public policy issues, Genentech argued that licensees always have the freedom to challenge "bad patents," provided they stop royalty payments. In addition, anyone, including a licensee, can request that the Patent Office re-examine the validity of a patent. Because other mechanisms for challenging unworthy patents exist, fears of innovation being stifled are grossly exaggerated.

Moreover, if MedImmune's rule were adopted, licensees would be unfairly bestowed with the inequitable right to challenge the validity of the licensed patents without incurring any real risk. Thus, the balance of power between a licensor and a licensee in challenging a patent, which *Lear* sought to equalize by eliminating the doctrine of licensee estoppel, would be unfairly and dramatically tipped in favor of licensees.

Clearly, how the Supreme Court resolves the issues in this case could profoundly affect all licensees and licensors that rely upon the U.S. patent system for certainty. Those companies that license very complex patents associated with the development and manufacturing of important drugs, biologics, and medical devices might be especially hard hit.

If the Federal Circuit is upheld in *MedImmune v. Genentech*, patent licensees will continue to run the risk of being sued for willful infringement (and risk an injunction) if they breach their license to challenge the licensed patents.

On the other hand, if the Supreme Court follows the proposed MedImmune rule or some variation of it, the whole system under which innovative companies frequently license and build on one another's patents could be handicapped. Patent owners might become less willing to license out their patents. At a minimum, they might raise license fees to offset the greater risk of being sued.

Further, should the Supreme Court side with MedImmune, more and more licensors will want to think about suing for infringement immediately, instead of first "inviting" the alleged infringer to license (as is the general current practice). The goal would be to ensure that the granting of a license was part of a negotiated court-ordered settlement that would have some res judicata effect on the licensee.

Here's a rule of thumb: Take a careful look at any patent argument that would encourage more litigation, fewer licenses, and potentially less innovation.

John M. Vassiliades is of counsel in the Northern Virginia office of Morrison & Foerster. He is a member of the life sciences practice group and specializes in patent and technology transactions. He may be reached at jvassiliades@mofo.com. Morrison & Foerster has represented Celltech in the underlying litigation discussed here.